Remarks by Cong. Henry A. Waxman
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Introduction:

Good morning. It's a pleasure to join you here today.

I understand you all are particularly interested in hearing from me on the FDA, its performance, its direction and the issues it is confronting. I want to talk about that.

I also want to give you my perspective on the need to address other major problems facing the American health care system, including the rising cost of care and the uninsured, and my view of the likelihood of congressional action.

But first, I want to talk about Medicare and prescription drugs, because there is a lot of activity going on there, and the subject is a timely one.

This morning the President is having a White House event focused on Medicare and prescription drugs. Every day we hear that the Medicare conference is about to conclude. Major decisions are being made related to the specifics of drug coverage, the long-term structure of Medicare, improving the speed of generic drugs reaching the market, and reimportation of drugs from across our borders, not to mention myriad decisions on Medicare reimbursement policies.

Since I'm part of that beleaguered group known as Democrats in the House of Representatives, I'm learning about the conference decisions second hand—from reporters, from Senate colleagues, even from lobbyists—much as you are.

There is no bipartisanship in this process. Working behind closed doors with few representatives of the minority party, keeping decisions secret, bringing the bill to the floor without an opportunity for members of Congress or the public to see it and understand it, is a recipe for trouble.

It's not likely to result in good law. And it certainly is not the way to make changes in the health care program that is critical for every American senior, and affects every health care provider in the country.

Medicare:

No one can doubt that we need a prescription drug benefit in Medicare. Prescription drugs are no longer an add-on to care; they are a vital part of medical treatment. They are costly. They are most expensive for people who don't have some kind of third party coverage. And no group is more dependent on prescription drugs to treat both acute and chronic conditions than the elderly and disabled, the very population that Medicare serves.

But agreeing on the problem is very different than finding the right solution.

I think I reflect the views of most Democrats in the House, and indeed most in the Senate, when I see critical flaws in the bill that seems to be emerging from this conference.

First, both the Senate and House bills face a serious problem in terms of projected loss of employer-covered drug benefits for their retirees if this Medicare bill passes. We all know the pressure on retiree health costs, and we all know the existing trend of losing these benefits.

But an acceleration of this trend because of the enactment of this Medicare drug benefit--the Congressional Budget Office estimates more than one-third of retirees with drug coverage will lose it—is flat out unacceptable.

There is simply not adequate support in this bill for employers to maintain coverage. And the paucity of the Medicare benefit makes it certain that people losing their employer coverage for such skimpy Medicare coverage will be understandably very angry.

If we were really doing what the Republicans say they're for—a drug benefit like the one Members of Congress have—then we wouldn't be putting those with existing coverage at such risk.

Second—and this is critical in my view—any bill which undermines and jeopardizes the basic Medicare program under the cover of providing a drug benefit absolutely should not pass.

Whether we use technical terms like premium support, or use the rhetoric of competition, the fact is these changes turn Medicare into a voucher program. That is not acceptable to Democrats or seniors.

And it won't work.

Making it more expensive for people who want to stay in traditional Medicare is wrong. Making people pay different premiums depending on where they live is wrong. Taking away the assurance of a defined benefit for this very vulnerable population is wrong.

I oppose anything that breaks down the universality of the Medicare program. Denying the drug benefit to low income seniors covered by Medicaid, or income testing the premium for the part of the program where participation is voluntary, will lead to a fracturing of the risk pool. It contains all kinds of incentives to lead healthier and wealthier people out of the program. And it ends the uniform coverage that has been the hallmark and strength of Medicare since its enactment.

These changes might pass—I can't tell you that those who share my view will prevail.

But our disagreement with this policy is so profound that we will fight it with everything we have now, and we will continue to fight it at every future opportunity.

Third, the basic structure of the Republican plan is flawed. It doesn't add a prescription drug benefit to Medicare. Instead, it requires seniors to enroll for coverage either in an HMO or to get coverage through private at-risk plans that offer drug-only insurance coverage.

These latter are entities that don't exist today, and nobody knows if they will develop.

I think it is highly questionable that we will get the plans we need. I think they will end up costing the government more. And I think we'll find many areas where a choice of plans won't be available to Medicare beneficiaries, maybe not any plans at all.

That's why there is so obviously a need for a Medicare fall-back plan—a fact recognized in the Senate bill, and a major source of contention between the two Houses.

But the very complexity of trying to set up competition plans offering drug benefits—whether drug only plans or HMOs—will be a source of trouble when this program is implemented. The rules about when the fallback plan can come into place, and when it must leave, will be its own source of trouble.

The whole scheme will be confusing to seniors and complex to run.

Fourth, in my view, we clearly need a better benefit, and more help for the low-income.

The benefit in both bills, with so-called donut holes in coverage, is simply inadequate, and Medicare beneficiaries are going to be very unhappy with it.

Finally, let me say a word about cost containment.

As you know, there is great frustration with the cost of prescription drugs in this country. That frustration is very visible with the elderly because so many of them pay for their drugs out of pocket and pay the very highest prices. But the frustration is broader than that.

Americans are angry they pay so much more for their drugs than people in other countries pay for the very same drug. They are sick and tired of being taken advantage of. That is why the proposals to allow the reimportation of drugs have such political power.

It is incredible to me that we can see this concern over drug prices, but refuse to use the purchasing power of programs like Medicare to negotiate reasonable prices, like other countries do.

Instead, the answer of my Republican colleagues in the conference is to define cost containment as setting a cap on the general revenue contribution to the Medicare program.

That is not cost containment—that is cost shifting onto the most vulnerable, the beneficiaries.

And that proposal is the final poison pill in the bill which truly undoes the guarantee of Medicare.

FDA:

The issue of reimportation of prescription drugs is a good segue to the challenges facing the FDA. Let's talk some about that critical agency.

The FDA has long been known as one of premier regulatory agencies in the federal government. It is also one of the most trusted. A recent poll found that while only 40% of Americans have confidence in the government as a whole, 80% trust the FDA.

What is that trust based on? It is based on Americans' belief that the FDA applies rigorous standards in approving new medical products and new food additives. It is based on their belief that the FDA steadfastly enforces the law to ensure that the food on their supermarket shelves is safe and the medicine on their pharmacy shelves is effective.

That trust, and the actions the agency takes to justify it, is vital, not only to American consumers, but to regulated industries as well.

FDA's history shows that when consumers are exposed to scams, unjustified claims, or needlessly dangerous products, consumer confidence evaporates. Over the long term, consumers and industry either suffer or advance together.

Despite the value of a strong FDA to both consumers and industry, attempts to weaken its power are constant and come from many directions.

The agency has been perennially starved of resources. For example, the FDA oversees the safety of 80% of the food consumed in the U.S. with only 20% of the nation's food safety budget. The lack of resources undermines the FDA's ability to enforce requirements as well as its ability to hire and retain high-quality scientists.

The FDA's workload has increased steadily over the past decade, as it has confronted the rapid evolution of new technologies, the emergence of the internet, and the globalization of trade. During this same period, however, the agency's staffing levels have substantially decreased. This is not good news for an industry that wants its products quickly approved.

Congress has taken some steps to address the resources gap, by creating user fee programs. Under these programs, manufacturers pay a substantial fee to the agency in exchange for reviewing their products. The prescription drug user fee program has largely been a success, resulting in both greater revenue for the agency and speedier drug approvals for industry. A recent attempt to create a similar program for medical devices has met with less success: Congress failed to appropriate the funds necessary to make the program viable.

While user fee programs can sometimes fill specific gaps in the agency's funding, most of the FDA's programs will remain underfunded until Congress provides adequate appropriations for the agency.

Other attempts to weaken the FDA's authority are more direct. The courts have been increasingly aggressive in restricting the FDA's authority to regulate product advertising, citing First Amendment concerns.

The Bush administration has jumped at this opportunity to put the commercial speech rights of industry before the health interests of consumers. In a series of actions, the Administration has begun to cut back the agency's traditional authority to protect consumers from misleading advertising of foods and drugs. .

I believe that all of these attempts to weaken the FDA are misguided, not only for the health of consumers but for the industry as well. When the public begins to see that the FDA is allowing companies to market unsafe products and to make inflated claims that are later shown to be untrue, they will lose confidence in those product categories.

I earlier talked about the frustration that Americans feel about the high price of prescription drugs. Pricing issues are not the traditional domain of the FDA. But the pressure to control drug costs has begun to impinge on the agency in a variety of ways.

I want to touch on a few of those: reimportation of approved drugs, approval of generic drugs, and testing drugs for comparative effectiveness.

Let me turn first to the growing support for reimportation of drugs from Canada and other countries. Despite my strong belief that current prescription drug prices are untenable, and that Americans are entitled to affordable drugs, I have been reluctant to embrace reimportation as the answer. I want to be very clear that I do not in any way endorse the price discrimination practiced by the pharmaceutical industry in this country. It is unconscionable that uninsured citizens in this country, who can least afford it, pay double or even triple for prescription drugs what the citizens of other countries pay.

So I sympathize with the goal of reimportation. Nevertheless, I believe it is not the best way to lower drug prices. I have looked hard at how reimportation would work and I remain concerned that it poses real safety risks to American consumers. The Washington Post series on the vulnerability of our current system to counterfeit and substandard drugs should make all of us concerned about what will happen if we open our borders to millions of shipments of drugs.

Having said that, I frankly think some version of reimportation will be included in the Medicare legislation. The pressure to permit reimportation has become if anything even more formidable since the surprisingly large House vote on the issue. Each day a new governor or mayor announces his or her intention to begin buying drugs from Canada.

Let's be completely clear about this: the pharmaceutical industry could make this problem disappear tomorrow, without any of the legislative interference they dread so much. We wouldn't need to consider relaxing the rules on reimportation if they would voluntarily stop discriminatory pricing against Americans, particularly seniors and the uninsured.

Instead, the pharmaceutical industry may lose a legislative battle it really cares about. If I were in the industry, I'd take that as a serious warning that the public is fed up.

There are other ways that can help.

Though certainly not the complete solution to high drug prices, the FDA does have an influence over one important means of curtailing runaway spending on drugs. The FDA's authority to approve generic copies of brand name drugs is perhaps the most significant power it has to affect drug prices. Its administration of the 19-year old Hatch-Waxman Amendments directly affects how soon generic drugs enter the market and conversely how long brand name companies can charge monopoly prices.

The Hatch-Waxman Amendments were designed to balance the need to speed access to low-cost generics with the need to reward innovation. This balance is achieved by providing specific periods of exclusive marketing to brand name drugs, after which generic drugs are supposed to become available.

If there were reliable access to generic versions of major drugs at the end of statutory period, it would help diminish some of the consumer frustration with prescription drug prices. At the moment, however, access to generics is <u>not</u> reliable. Unfortunately, many brand name drug companies have been exploiting loopholes in the law to delay the entry of generic drugs far longer than intended by Congress. I don't think it's a coincidence that these companies began trying to extend their monopolies on existing drugs just as their pipelines for new drugs were drying up.

In the last year, the FDA issued a rule which would limit the ability of brand name companies to extend their monopolies through the so-called "30-month stay," a legal maneuver that delays generic market entry through the filing of lawsuits.

While I believe that this rule is a needed step toward limiting exploitation of loopholes in the law, the rule is vulnerable to legal challenge. In addition, it doesn't go far enough to make sure that generic products enter the market as quickly as the Hatch-Waxman law intended.

Stronger legislation to address abuses is being negotiated in the Medicare conference. I strongly support the Senate version of this legislation, which ensures that generic companies have a way to resolve patent infringement issues quickly, rather than allowing these issues to unnecessarily delay market entry.

There is another method of reducing prescription drug expenditures that is potentially within the federal government's power: providing reliable information to the public on the comparative effectiveness and cost effectiveness of prescription drugs.

You've probably seen ads for Nexium, AstraZeneca's "new" drug for heartburn. The purpose of these ads is to make you think that Nexium is superior to Prilosec, AstraZeneca's older heartburn medication. In fact, Nexium and Prilosec are virtually identical drugs.

There is one significant difference between the two drugs however: the price. Nexium is still protected by patents, while Prilosec is not, and generic competition has substantially lowered Prilosec's price.

Is there any scientific evidence that Nexium is superior to Prilosec? No. Nor is there any objective source of information out there to help doctors determine which drugs are the most effective. In the absence of such information, drug companies spend tens of millions of dollars to advertise the supposed advantages of their latest and most expensive drugs, knowing that patients and doctors will be convinced to buy them.

The costs of this to patients and to our health care system are enormous.

We cannot afford to let pharmaceutical companies provide the only source of information on which drugs are safer or more effective than other drugs. In a modest step to help address this, Tom Allen, Jo Ann Emerson and I have introduced legislation to authorize the NIH and the Agency for Healthcare Research and Quality to provide physicians with that information.

The bill does not tell anyone what drugs to prescribe or what drugs to pay for. It simply provides objective, scientific information about how drugs

compare. It's a sad commentary that the drug industry opposes the legislation, and evidently fears letting doctors have this information.

Let me touch on one final issue related to the marketing of prescription drugs. One of the principal reasons why reimportation poses such risks is the rise of the Internet. It's one thing to take a bus to Canada, walk into a pharmacy, and buy a drug. It's quite another to go online, find a website claiming to be a Canadian pharmacy and order a drug through the mail. The chances that the Canadian pharmacy is in fact an illicit Chinese or Indonesian drug supplier are getting higher every day.

The emergence of internet pharmacies as a major market force has brought with it another problem. A great many internet pharmacy sites now advertise that they will sell you prescription drugs without a prescription. These web sites occupy a dark and dangerous corner of the U.S. health care system. With the simple click of a mouse, consumers can purchase virtually any prescription medication without knowing who is hosting the web site, who is writing the prescription, or who is dispensing the drug.

It should not be necessary to require 50 separate lawsuits to shut down every dangerous internet site. Federal legislation is sorely needed to give the federal government clear authority to take action against these sites. I believe there is growing interest in Congress in addressing this problem.

Other health care issues:

I have already talked longer than I intended, and I want to leave some time for questions. But let me make just a few brief comments on some other issues that in my view cry out for Congressional action.

Tobacco. The first is tobacco. Giving FDA the authority to regulate this product should be a priority for anyone concerned about the public health. It is incredible that a product that is the leading preventable cause of death in this country is essentially unregulated.

We need to stop the efforts to get kids to smoke. We need to help smokers to quit. It is just that simple.

We can see on the horizon the next generation of issues: claims by companies that they are now marketing a reduced risk product. It we let these products on the market, making claims that have not been validated by the FDA, we are likely to repeat the disastrous experience with light and low tar products and continue to play roulette with the public health.

Will anything happen? Obviously, the industry has successfully stymied a strong bill for years, and it won't be easy to change that situation.

I'm cautiously hopeful that the recent indications of interest, particularly by Senator DeWine and Senator Gregg, can help us give FDA the clear and strong authority the agency needs.

The Uninsured. Let me also comment on the issue of the uninsured.

The recent reports that we now have 43 million uninsured Americans in this country reflect a failure of this society to provide a very basic right to its citizens.

No issue should be higher on the agenda of the Congress than providing a way for all Americans to be assured of adequate, affordable health care coverage.

Nobody knows better than the American businesses that cover their employees the cost they bear because we have so many uninsured. It strains our health care system, it puts critical health care providers at risk, and most of all, it takes a tremendous human toll on those who cannot get the access they need to health care.

It has long been a tenet of the Democratic party that all Americans should have health insurance coverage. Whether we do it through public programs—like extending Medicare, or whether we do it by strengthening and extending our employer-based insurance system is less important to me than that we get the job done.

What we cannot do is back solutions that will undermine and weaken what we've got, and put the individual purchaser at the mercy of the individual insurance market. What we cannot do is destroy the Medicaid program which now effectively acts as a safety net for 51 million of the

poorest and most vulnerable Americans. What we must do is build on our current system to stop its erosion and extend its reach.

I expect the Republican majority to pay lip service to the problem, but put their eggs in the basket of an inadequate, unregulated tax credit system that will not significantly reduce the number of uninsured and which may well lead to the destruction of the group insurance market and the employer-based system now in place.

I hope they won't succeed.

Now let me take some questions.